

REMARKS**Status of the Claims**

Claims 1-23 are pending in the application. Claims 1-8 and 17-23 have been elected for further prosecution. Consequently, claims 9-16 have been withdrawn. Claims 1-8 and 17-23 have been amended without prejudice or disclaimer. New claims 24-26 have been added. Claim 24 depends from claim 17 and finds support in the specification at least on page 8, lines 18-21. New claims 25-26 recite the specific monoclonal antibody pair of M52 and M271. Support for the amendments and new claims can be found at least on pages 8-11, 14-19, 29-30, 32-35, 38-40 and in Examples 4-10 of the specification.

Upon entry of the present amendment, claims 1-8 and 17-26 will be pending and under consideration. Reconsideration of the pending claims in view of the following amendments and remarks is respectfully requested. No new matter is added by way of the present amendments.

Rejections Under 35 U.S.C. §112, second paragraph (Indefiniteness)

Claims 1-8 have been rejected as being indefinite for claiming both a method and a strip device. In response, claim 1 has been amended to delete reference to a strip device. The claimed methods can be practiced utilizing a number of different embodiments, and are not limited those requiring a strip device. Claims 2-3 and 5-8 have also been amended to more clearly recite certain aspects of the claimed methods. Support for these amendments can be found at least on pages 8-11, 14-19, 29-30, 32-35, 38-40 of the specification.

Claim 17 has been rejected as being vague for failing to claim components for a device. Claim 21 has been rejected for failing to provide antecedent basis for “the solid support.” Claim 22 has been rejected for failing to provide antecedent basis for “the ratio.” Finally, claim 23 has been rejected for not providing a connection between the claimed monoclonal antibodies and the device. In response, claim 17 has been amended to recite:

A device comprising a detector section having a mobilizable antibody specific for PAMG-1 which is upstream from a capture section having an immobilized antibody specific for PAMG-1, wherein the capture section also comprises at least one other monoclonal anti-PAMG-1 antibody exhibiting lower binding specificity to PAMG-1 than the mobilizable and immobilizable PAMG-1 antibodies, intended to be used in combination with the mobilizable and immobilizable PAMG-1 antibodies,...

Claim 17 has been amended to recite certain structural features of the claimed device, i.e., to recite a “device comprising *a detector section* having mobilizable antibody specific for PAMG-1 which is upstream from *a capture section* having an immobilized antibody specific for PAMG-1” (emphasis added). This amendment is supported by the specification at least on page 24, lines 1-19, and on pages 38-40. In view of the amendment of claim 17, claim 21 has been cancelled.

With respect to claim 22, the ratio of the amounts of the two antibodies described in claim 17 is inherent and as such does not require an explicit prior citation in claim 17 to provide antecedent basis. However, in order to advance prosecution, and without conceding the validity of the rejection, claim 22 has been amended to recite “wherein a ratio of the antibodies.” Finally, claim 23 has been amended to recite “wherein a the monoclonal antibody” in order to clarify the relationship of the recited antibodies to the device of claim 17.

In view of the amendments and argument provided herein, it is believed that all of the indefiniteness rejections have been overcome.

Rejections Under 35 U.S.C. §102(b)

Claims 17-22 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Fuks *et al.* (U.S. Patent No. 5,877,029) (“the ‘029 patent”). According to the Examiner, the ‘029 patent discloses a test strip device for performing sandwich immunoassays to detect IGFBP-1 (also known as PAMG-1). The Examiner concludes that the test strip described in the ‘029 patent contains mobile and immobile monoclonal antibodies that bind to IGFBP-1 and that the mobile antibodies are conjugated to a marker such as gold sol particles.

In response, claim 17 has been amended to set forth an additional technical feature of the claimed invention, *i.e.*, to recite “other monoclonal anti-PAMG-1 antibodies” as in claim 1, and also to recite that the one or more other antibodies “exhibit a lower binding specificity to PAMG-1 than the mobilized and immobilized antibodies.”

Support for this amendment can be found at least on pages 8-11, 14-19, 29-30, 32-35, 38-40 and in Examples 4-10 of the specification.

Nothing the ‘029 patent teaches utilizing such an additional monoclonal antibody, much less devices and methods for detection of PAMG-1 using combinations of antibodies of varying degrees of specificity that can effectively minimize the likelihood of false-positive and false-negative results as presently claimed.

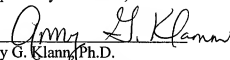
CONCLUSION

In view of the above remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. Applicants reserve the right to pursue the cancelled and/or non-elected subject matter in one or more continuation or divisional applications.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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